

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO. BOX 1450 Alexandria, Virginia 22313-1450

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/806,801	04/04/2001	Staffan Folestad	1103326-0659	6014	
7470	7590 09/17/2003				
WHITE & CASE LLP			EXAMINER		
PATENT DEI 1155 AVENU	PARTMENT IE OF THE AMERICAS		JACKSON,	JACKSON, ANDRE K	
NEW YORK, NY 10036			ART UNIT	PAPER NUMBER	
			2856		
			DATE MAILED: 09/17/2003	3	

Please find below and/or attached an Office communication concerning this application or proceeding.

	<u> </u>	<b>-</b>				
	Application No.	Applicant(s)				
	09/806,801	FOLESTAD ET AL.				
Office Action Summary	Examiner	Art Unit				
	André K. Jackson	2856				
The MAILING DATE of this communication ap	ppears on the cover sheet	with the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a replaced in the provision of the pro	.136(a). In no event, however, may ply within the statutory minimum of t d will apply and will expire SIX (6) M te, cause the application to become	a reply be timely filed  hirty (30) days will be considered timely.  ONTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on 21	<i>July 2003</i> .					
2a)⊠ This action is <b>FINAL</b> . 2b)□ T	his action is non-final.					
3) Since this application is in condition for allow						
closed in accordance with the practice under Disposition of Claims	r Ex parte Quayle, 1935 (	C.D. 11, 453 O.G. 213.				
4)⊠ Claim(s) <u>1-3,6-23,25 and 26</u> is/are pending in						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-3,6-23,25 and 26</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/Application Papers	or election requirement.					
9) The specification is objected to by the Examin	or.					
10) The drawing(s) filed on is/are: a) acce		the Examiner				
Applicant may not request that any objection to the						
11) The proposed drawing correction filed on						
If approved, corrected drawings are required in re						
12) The oath or declaration is objected to by the E	xaminer.					
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreig	gn priority under 35 U.S.C	C. § 119(a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documer	nts have been received.					
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the price application from the International B</li> <li>* See the attached detailed Office action for a lis</li> </ul>	ureau (PCT Rule 17.2(a)	).				
14) Acknowledgment is made of a claim for domes	stic priority under 35 U.S.	C. § 119(e) (to a provisional application).				
a) ☐ The translation of the foreign language pr 15)☐ Acknowledgment is made of a claim for domes	• •					
Attachment(s)	, ,					
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) D Notice	w Summary (PTO-413) Paper No(s) of Informal Patent Application (PTO-152)				

Application/Control Number: 09/806,801

Art Unit: 2856

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1,3,6,7,10,11,17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad.

Regarding claim 1, Hammond et al. disclose "Spectrophotometric analysis" which has a means for feeding one sample through at least one predetermined analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. What is not disclosed by Hammond et al. is where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However,

Art Unit: 2856

Trygstad discloses in "Measurement of transmission spectra of pharmaceutical tablets" where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position as taught by Trygstad. By adding this feature the artisan would be able to analyze tablets of various sizes.

Regarding claim 3, Hammond et al. disclose where the first and second holding parts do not contact the sample in the open position (Column 12, lines 22-52).

Regarding claim 6, Hammond et al. disclose where the first and second holding parts each define a first and second compartment, which together define a predetermined volume (Figure 2).

Regarding claim 7, Hammond et al. disclose where the means for feeding samples through the analyzing position comprises one prealignment means for receiving and holding a sample during transport of the sample to the analyzing position (Figure 2).

Send it in// Sequentially Regarding claim 10, Hammond et al. disclose where the prealignment means comprise a spring-loaded arm for embracing the sample (Figure 2).

Regarding claim 11, Hammond et al. disclose where spring-loaded arm and a part of the feeding means are provided with an indentation for receiving the sample (Figure 1).

Regarding claim 17, Hammond et al. disclose where the sample is a solid dosage form (Figure 2).

Regarding claim 26, Hammond et al. disclose where the dosage is a tablet (Figure 2).

Claims 2,8,9,12-16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad as applied to claim 1 above and in further view of Schilling.

Regarding claim 2, Hammond et al. does not disclose where the first and second holding parts are located on opposite sides of the sample when in the closed position. However, Trygstad discloses where the first and second holding parts are located on opposite sides of the sample when in the closed position (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts are located on opposite sides of the sample when in the

closed position as taught by Trygstad. By adding this arrangement the sample would remain in a stable position.

Regarding claims 8 and 9, Hammond et al. does not disclose where the pre-alignment means comprises an elastically compressible member for flexibly engaging the sample. It is considered a design choice to have an elastically compressible member for flexibly engaging the sample to keep the sample from chipping or breaking.

Regarding claim 12, neither Hammond et al. nor Trygstad disclose where the means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample. However, Schilling discloses a "Sorting arrangement" which has a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample as taught by Schilling since it would make it easier to analyze more samples in a shorter period of time.

Regarding claim 13, neither Hammond et al. nor Trygstad disclose where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed. However, Schilling discloses where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the rotating feeder wheel is connected to a sample receiver which provides the feeder with samples to be analyzed as taught by Schilling since it would provide an even distribution of tablets.

Regarding claim 14, Hammond et al. does not disclose where the sample receiver is an on-line sample receiver and provides the prealignment means with samples. However, Schilling discloses where the sample receiver is an on-line sample receiver and provides the prealignment means with samples (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is an on-line sample receiver and which provides the pre-alignment means with samples as taught by Schilling since this would help to give an accurate measurement for the sample.

Regarding claim 15, Hammond et al. does not disclose where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples. However, Schilling discloses where the sample receiver is an at-line sample receiver, which provides the pre-

alignment means with samples. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples as taught by Schilling since this would aid in having the measurement of the samples more accurate.

Regarding claim 16, Hammond et al. does not disclose where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel. However, Schilling discloses where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel as taught by Schilling since this would make it easier to sort the tablets.

Art Unit: 2856

Regarding claim 25, Hammond et al. does not disclose where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process. However, Schilling discloses where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process as taught by Schilling since this would ease in the measuring of the sample.

 Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Schilling and Trygstad.

Regarding claim 18, Hammond et al. disclose a means for temporarily fixing the sample at the analyzing position. What is not disclosed by Hammond et al. is feeding a sample sequentially through the sample presentation apparatus. However, Schilling discloses where feeding a sample sequentially through the sample presentation apparatus (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where feeding a sample sequentially through the sample presentation apparatus as taught by Schilling since this would make it easier for the samples to be placed in the analyzing position. Hammond et al. does not

disclose an open position to allow the sample to be transported to an ejection position. However, the invention of Hammond et al. has to have the holding parts open in order to eject the sample to place another one in place. What is not disclosed by Hammond et al. is where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses where the first and second holding parts define apertures within the parts (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts as taught by Trygstad. By adding this feature the artisan would be able to analyze tablets of various sizes.

Regarding claim 19, Hammond et al. disclose where the measurement is performed by irradiating the sample with at least one measuring beam while the sample is temporarily fixed (Figure 2).

Regarding claim 20, Hammond et al. disclose where the measurement is an optical measurement (Abstract).

Regarding claim 21, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 22, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 23, it is considered a design choice and well within the purview of the skilled artisan to have the radiation beam a microwave beam since this would give the artisan a beam with a shorter wavelength and a more precise measurement.

## Response to Arguments

Applicant's arguments with respect to claims 1-26 have been considered but are most in view of the new ground of rejection.

Regarding claim 1, Applicants argue that Hammond et al. does not have a "means for feeding one or more samples sequentially".

However, Hammond et al. disclose that a means for positioning the tablet can be done by vibrations (Columns 4-5). The claim calls "for feeding one or more samples sequentially" with that limitation being written in the alternative hence, Hammond et al. disclose feeding one sample (Columns 4-5).

6. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE** 

Art Unit: 2856

**FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to André K. Jackson whose telephone number is (703) 305-1522. The examiner can normally be reached on Mon.-Thurs. 7AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (703) 305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

September 15, 2003

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 2800